



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,038	10/02/2003	John A. Mikszta	035510/319556 (P-5331P1P1)	1660
47656 7590 11/27/2007 BECTON, DICKINSON AND COMPANY (ALSTON & BIRD LLP) 1 BECTON DRIVE MC 110 FRANKLIN LAKES, NJ 07417-1880			EXAMINER MENDEZ, MANUEL A	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 11/27/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ED

Office Action Summary

Application No.

10/679,038

Applicant(s)

MIKSZTA ET AL.

Examiner

Manuel Mendez

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner's Comment

After a careful review of applicant's comments dated July 9, 2007, the examiner concurs with the arguments submitted, and hereby vacates the Office Action mailed on April 9, 2007. Accordingly, this Office Action is not a Final Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenburg**, U.S. Patent No. 6,623,457, in view of **Kim et al.**, U.S. Patent No. 6,309,650 and in further view of **Duke et al.**, U.S. Patent No. 5,830,463.

The Rosenberg patent discloses a method and apparatus for the transdermal delivery of a substance into the human body comprising of microneedles (figure 9, item 126). In column 1, lines 9-12, the specification states that "the invention is directed to a method and apparatus for delivering a pharmaceutical agent such as a **vaccine** to a patient through the stratum corneum". Based on the teachings of Rosenberg, any fluid vaccine could be administered by inserting the vaccine in the reservoir of syringe (110) in figure 9 and simply pressing plunger (116).

The Rosenberg patent does not specifically disclose or name the vaccines that are used with the microneedle apparatus, and more specifically, the Japanese

Encephalitis vaccine. However, the Japanese Encephalitis vaccine is a vaccine that is well known in the medical infusion arts as evidenced by the teachings of Kim et al. More importantly, in column 7, lines 33-34; the specification of Kim et al. discloses that "JE vaccines are prepared as injectables". Accordingly, for a person of ordinary skill in the art, modifying the syringe reservoir disclosed by Rosenberg in figure 9 to include the Japanese Encephalitis vaccine, as taught by Kim et al., would have been considered obvious in view of the fluidity characteristics of the vaccine, and moreover, the injectability of the vaccine.

Additionally, based on the teachings of the cited references, for a person of ordinary skill in the art, using the apparatus disclosed by Rosenberg to infuse a well known vaccine, such as the Japanese Encephalitis vaccine, would have been obvious to try since the artisan in the art would have been choosing from a finite number of identified "infusion" solutions with a reasonable expectation of success.

Claims 64-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Rosenburg**, U.S. Patent No. 6,623,457, in view of **Kim et al.**, U.S. Patent No. 6,309,650 and in further view of **Duke et al.**, U.S. Patent No. 5,830,463 as applied to claim 61-63 above, and further in view of **Odell et al.**


The Rosenberg, Kim et al., and Duke et al. patents do not disclose a kit or package that includes an infusion apparatus and with a reservoir to retain fluid. Based on the teachings of Rosenberg, for a person of ordinary skill in the art, modifying the Kit shown in figure 9 of Odell et al. with a microneedle infusion apparatus, as taught by

Rosenburg, and a fluid vaccine, as taught by Kim et al., would have been considered obvious in view of the proven conventionality of packaging infusion devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Manuel Mendez
Primary Examiner
Art Unit 3763